IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

IN RE ST. JUDE MEDICAL, INC., SILZONE HEART VALVES PRODUCTS: LIABILITY LITIGATION

MDL DOCKET NO. 1396

JOINT STATUS CONFERENCE REPORT

(Status Conference-- July 24, 2002, 12:30 p.m.)

The parties have met and conferred and submit the following status report to the Court.

1. STATUS OF CLASS CERTIFICATION MOTION

Plaintiffs filed and served their motion for class certification, including supporting Memorandum of Law and Appendix, on May 3, 2002. Defendants filed and served their opposition thereto on June 17, 2002. Pursuant to the Court's order at the last Status Conference on June 25, 2002, Plaintiffs' Reply Memorandum is currently due on August 16, 2002. The hearing on the class certification motion is currently scheduled for September 10, 2002.

2. STATUS OF WRITTEN DISCOVERY

Documents. On or about July 12, 2002, Defendants produced CD-ROM's 40-47 containing documents purportedly responsive to Plaintiffs' Initial

Set of Merits Discovery Document Requests. Defendants have also interposed numerous objections to Plaintiffs' Document Requests, most of which Plaintiffs regard as being without merit. Plaintiffs wrote to Defendants' counsel on June 28, 2002 explaining that many of Defendants' objections were not, in Plaintiffs' view, well taken and are, in fact, unacceptable.

Defendants disagree and contend that because many of Plaintiffs' document requests, as currently phrased, are vague, ambiguous, overly broad and not calculated to lead to the discovery of admissible evidence, Defendants' Defendants responded to Plaintiffs' June 28, 2002 objections are proper. correspondence on July 18, 2002. Objections notwithstanding, Defendants intend to make a full and complete production of documents to Plaintiffs. Other than documents which relate to products that are not issue in these proceedings and documents which are protected from disclosure by the attorney-client or attorney work product privileges, no documents are being withheld based upon the asserted objections. Plaintiffs have requested further clarification from Defendants concerning the scope of such withheld documents and the parties have agreed to meet and confer. Documents that have been withheld on privilege grounds will be identified on a privilege log which will be produced to Plaintiffs.

Plaintiffs have advised Defendants' counsel in reply correspondence dated July 18, 2002, that, in view of the foregoing, Plaintiffs position is that Defendants' insistence on maintaining their objections is inappropriate. Plaintiffs also note that Defendants have represented in their objections that they have not yet completed their internal gathering of facts and documents. Plaintiffs question the appropriateness of such an objection at this juncture. Plaintiffs have asked Defendants to advise as to when this review will be complete.

Interrogatories. Defendants served their objections to Plaintiffs' First Set of Merits Interrogatories on or about June 24, 2002. As in the case of the document requests, Plaintiffs believe most of Defendants' objections to the interrogatories to be unwarranted. Plaintiffs communicated their position to Defendants by letter dated June 28, 2002.

Defendants disagree and contend that because many of Plaintiffs' interrogatories, as currently phrased, are vague, ambiguous, overly broad and not calculated to lead to the discovery of admissible evidence, Defendants' objections are proper. Defendants responded to Plaintiffs' June 28, 2002 correspondence on July 18, 2002. Defendants' substantive responses to the First Set of Interrogatories are due to be served on July 22, 2002. Defendants represent that no information is being withheld based upon the asserted

- 3 -

objections, other than documents which relate to products that are not issue in these proceedings. Plaintiffs have requested further clarification from Defendants concerning the scope of such withheld documents and the parties have agreed to meet and confer.

In view of the foregoing, Plaintiffs' position is that Defendants' insistence on maintaining their objections is inappropriate. Plaintiffs also note that Defendants have represented in their objections that they have not yet completed their internal gathering of facts and documents. Plaintiffs question the appropriateness of such an objection at this juncture. Plaintiffs have asked Defendants to advise as to when this review will be complete.

3. OTHER PENDING DISCOVERY MATTERS

A. Depositions

Plaintiffs will take the depositions of four Spire Corporation employees in August, 2002. The depositions of Dr. Piran Sioshansi and Ray Bricault will be taken on August 7 and 8, 2002. The depositions of Eric Tobin and John Barry are scheduled for August 22 and 23, 2002.

In the related Ramsey County Silzone case of *Nickerson, et al. v. St. Jude Medical, Inc., et al.,* Plaintiffs will take the deposition of cardiovascular surgeon Dr. G. Phillip Schoettle on August 1, 2002 in Memphis.

Plaintiffs intend on tendering a list of additional deposition notices in the near future.

B. Status of Third Party Discovery

The document production from the FDA is ongoing. Defendants represent that they have produced to Plaintiffs all documents produced by the FDA through July 17, 2002. Additional documents from the FDA were received by Defendants' counsel on July 18, 2002 and are being reviewed.

Plaintiffs have issued a document subpoena to Koppes & Partners Advertising, Inc., an advertising agency involved in the advertisement of Silzone products.

Plaintiffs also have an outstanding subpoena to Dr. Steven Goodman, a scientist in Wisconsin, to Dr. Goodman's former employer, the University of Connecticut Health Center and to Dr. Schoen, who has through his counsel interposed numerous objections to the subpoena. Resolution of those objections is being addressed.

Additionally, Plaintiffs' subpoena to AVERT/University of Pittsburgh has resulted in the production of two CD-Rom's of the subject patient files. Copies have been sent to Defendants' counsel. The AVERT production is not yet complete and is ongoing.

Plaintiffs believe additional third party discovery is warranted and necessary and will be issuing same as appropriate.

Defendants propose that a protocol be agreed to establishing a process by which documents received from third parties are bates labeled and a mechanism by which Defendants can assert confidentiality over their documents in the custody of third persons which Defendants believe are confidential. Plaintiffs contend that any claims of confidentiality should be asserted by the parties affected. Defendants do not understand what Plaintiffs mean by this statement.

C. Confidentiality Designations

After the exchange of multiple correspondence between the parties in an effort to meet and confer concerning the appropriateness of treating as confidential various categories of documents, Defendants have submitted a list of categories they refuse to concede are not confidential.

Plaintiffs' position is that by correspondence dated June 27, 2002, Plaintiffs informed Defendants that if they intend to insist on the confidentiality of such documents, they should bring a motion before the Court seeking to protect such confidentiality, pursuant to the procedure outlined in Pre-Trial Order 5 concerning confidentiality. Plaintiffs have fairly identified the disputed documents and designations by category and now, by their correspondence dated July 12, 2002, Defendants have continued to insist on maintaining such documents as

confidential. Accordingly, Plaintiffs submit, it is incumbent on Defendants under Par. 16 of Pre-Trial Order 5 now to move timely for a protective order or lose the confidentiality designation as to these categories of documents.

Defendants' position is that by their correspondence dated July 12, 2002, Defendants advised plaintiffs that each of the categories of documents that remain in dispute between the parties constitutes "commercially and/or competitively sensitive information of a nonpublic nature". Defendants submit that pursuant to paragraph 2 of Pretrial Order No. 5, the confidentiality designations are proper.

Having reached an impasse in negotiations on these specific categories, Defendants submit that paragraph 16 of Pretrial Order No. 5 obligates plaintiffs to specifically identify which documents within the disputed categories they contend are not entitled to a confidentiality designation. Defendants, by virtue of their July 12, 2002 correspondence, requested Plaintiffs to identify such documents. It is Defendants' position that Plaintiffs have not done so.

4. STATUS OF PRETRIAL ORDERS

A. Proposed Common Benefit Fund Order

The parties have come to agreement on most of the language of a proposed order addressing the creation of a "common benefit fund." However, the parties have reached an impasse over language in Section 2.e of the proposed order that has to do with the disclosure of the balance of the fund to Plaintiffs' counsel on a periodic (bi-monthly) basis. Plaintiffs believe it is well established practice and

sound business for Lead Counsel to know what monies are in the fund. Defendants contend that given the relatively small number of individual personal injury cases pending in these proceedings, even the periodic (bi-monthly) disclosure of the account balance proposed by Plaintiffs will jeopardize the confidentiality of the settlement amounts reached in individual cases. Because the parties cannot agree on this point, the parties request that the Court resolve the issue, after hearing from the parties briefly at the Status Conference. Plaintiffs' proposed Order Establishing Plaintiffs' Litigation Expense Fund is attached hereto as Exhibit A; St. Jude's proposed version of the order is attached hereto as Exhibit B.

5. CASE STATUS REPORT

Defendants' most recent report on federal and state court filings was forwarded to the Court by electronic mail on or about July 12, 2002 and reflects a current count of approximately 36 federal claims (9 class actions and 27 individual cases) and 89 state claims.

6. PREEMPTION DISCOVERY

Pursuant to the Court's instructions at the Status Conference held May 14, 2002, Plaintiffs have submitted, on July 22, 2002, a statement of discovery relevant to Defendants' affirmative defense of preemption. Defendants have not had the opportunity to fully review Plaintiffs' proposal concerning preemption - 8 -

discovery. Defendants will provide their response to Plaintiffs and the Court shortly.

7. SCHEDULING ORDER DISCUSSIONS

Pursuant to the Court's direction at the last status conference, the parties have made initial efforts to meet and confer concerning the development of an appropriate scheduling order for further proceedings in this matter. Specifically, the parties met and conferred telephonically on Monday, July 22, 2002. At the Court's request, this matter has been included on the agenda for further discussion at this Status Conference.

DATED:

July 22, 2002

ZIMIMMERMAN REED R.L.L.P

Bv:

Gordon Rudd, Jr., No. 222082

Plaintiffs' Liaison Counsel

CAPRETZ & ASSOCIATES

Bv:

James T. Capretz

Co-Lead Counsel for Plaintiffs

LEVY, ANGSTREICH, FINNEY, BALDANTE, RUBENSTEIN & COREN, P.C.

By:

Steven E. Angstreich

Co-Lead Counsel for Plaintiffs

GREEN SCHAAF & JACOBSON, P.C.

Bv:

Joe D. Jacobson

Lead Counsel for Class II Plaintiffs

an Steenburg

HALLELAND, LEWIS, NILAN, SIPKINS & JOHNSON, P.A.

Ву:

Tracy Van Steenburgh Attorneys for Defendant

St. Jude Medical, Inc.

CROSBY, HEAFEY, ROACH & MAY Professional Corporation

By:

David E. Stanley

Attorneys for Defendant St. Jude Medical, Inc.

| 1 | PLAINTIFFS' PROPOSAL | | |
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| 8 | UNITED STATES DISTRICT COURT | | |
| 9 | DISTRICT OF MINNESOTA | | |
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| 11 | IN RE ST. JUDE MEDICAL, INC., SILZONE HEART VALVES PRODUCTS MDL Docket No. 1396 | | |
| 12 | LIABILITY LITIGATION | | |
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| 15 | PRETRIAL ORDER NO. | | |
| 16 | TOTAL DE VOYENCE DE L'ENTERCOLE ENTON EXPENICE ELINIO TO | | |
| 17 | ESTABLISHING PLAINTIFFS' LITIGATION EXPENSE FUND TO COMPENSATE AND REIMBURSE ATTORNEYS FOR SERVICES PERFORMED AND EXPENSES INCURRED FOR COMMON BENEFIT | | |
| 18 | | | |
| 19 | The Court finds that this order is entered to provide for the fair and equitable | | |
| 20 | sharing among plaintiffs of the cost of special services performed and expenses incurred by | | |
| 21 | attorneys acting for the common benefit of all plaintiffs in this complex litigation. | | |
| 22 | Plaintiff's Litigation Expense Fund to be Established | | |
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| 24 | The Court shall establish insured interest bearing escrow accounts to receive and | | |
| 25 | disburse funds as provided in this order. The Court will, by future order, designate an escrov | | |
| 26 | agent to manage the account. These funds will be held as funds subject to the direction of the | | |
| 27 | Court. No party or attorney has any individual right to any of these funds except to the extent of | | |
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amounts directed to be disbursed to such person by order of the Court. These funds will not constitute the separate property of any party or attorney or be subject to garnishment or attachment for the debts of any party or attorney except when and as directed to be disbursed as provided by court order to a specific person. These limitations do not preclude a party or attorney from transferring, assigning, or creating a security interest in potential disbursements from the fund if permitted by applicable state laws and if subject to the conditions and contingencies of this order.

1. Assessment

- All Plaintiffs and their attorneys (except those exempted as provided a. herein) who, (i) either agree or have agreed – for a monetary consideration - to settle, compromise, dismiss, or reduce the amount of a claim; or (ii) with or without a trial, recover a judgment for monetary damages or other monetary relief, including compensatory and/or punitive damages, with respect to a St. Jude Medical, Inc. Silzone® related claim are subject to an assessment of the "gross monetary recovery," as provided herein.
- Defendants are directed to withhold this assessment from amounts paid to Ъ. plaintiffs and their counsel, and to pay the assessment directly into the fund as a credit against the settlement or judgment. If for any reason the assessment is not or has not been so withheld, the plaintiff and his counsel are jointly responsible for paying the assessment into the fund promptly.
- No orders, praecipes or notices of dismissal or discontinuance, of any c. plaintiff's claim, subject to this order, shall be filed unless accompanied by

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PROFESSIONAL CORPORATION

a certificate of plaintiff's and defendant's counsel that the assessment has been withheld and deposited into the fund.

- d. The Plaintiffs' Executive Committee ("Leadership Committee") shall provide Defendants' Liaison Counsel, plaintiffs' counsel, the escrow agent, the Court or its designee with a list of cases and/or counsel who have entered into written agreements with the Plaintiffs' Leadership Committee. In the event there is a dispute as to whether a case should be on the list, the Plaintiffs' Leadership Committee shall resolve the matter with the particular plaintiffs' counsel either informally or upon motion.
- e. In measuring the "gross monetary recovery":
 - i. Exclude court costs that are to be paid by the defendant,
 - ii. Exclude any payments to be made by the defendant on an intervention asserted by third-parties, such as to physicians, hospitals, and other health-care providers in subrogation related to treatment of plaintiff.
 - iii. Include the present value of any fixed and certain payments to be made in the future (except that, in lieu thereof, a plaintiff may agree to be assessed the appropriate percentage when and as future payments are received.)
- f. This Assessment Obligation:
 - i. Applies to all cases now pending, or later filed in, transferred to, or

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removed to, this court and treated as part of the coordinated proceeding known as In re: St. Jude Medical, Inc., Silzone® Heart Valves Products Liability Litigation including cases later remanded to a state court. The assessment in such cases shall be six (6) percent of the "gross monetary recovery," except for those cases described in subsections (iii) and (iv) below.

- ii. Applies to the other federal Silzone® cases which are not transferred to this court under MDL 1396 or which are transferred back to a transferor court by this Court or by the MDL panel for further proceedings. The assessment in such cases shall be six (6) percent of the "gross monetary recovery, except for those cases described in subsections (iii) and (iv) below.
- iii. Applies to cases in a state court to the extent so ordered by the presiding judge of that court, or in the event a state court plaintiff, through counsel, consents, by written agreement with the Plaintiff's Leadership Committee or Plaintiffs' Liaison Counsel, to be subject to an MDL fee assessment. The assessment in such state court cases is limited to six (6) percent of the "gross monetary recovery."
- iv. Shall not apply to cases removed from state court to federal court and then remanded to state court (based upon an order of improper removal) that have not at any time been transferred to MDL-1396 (unless subsection (iii)) above applies).

Relief from Obligation.

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hard copies or computerized images of documents from the defendants; to conducting "national" and "state" depositions; and to activities connected with the coordination of federal and state litigation. The fund will not, however, be used to pay for services and expenses primarily related to a particular case, such as the deposition of a treating physician, if such activity results in some incidental and consequential benefit to other plaintiffs.

- Payments will not exceed the fair value of the services performed or the d. reasonable amount of the expenses incurred, and, depending upon the amount of the fund, may be limited to a part of the value of such services and expenses.
- All payments required to be made shall be made by defendants to the e. escrow agent. Payment to the escrow agent shall fully discharge the defendants' obligation under this order. The payments to be made to the account shall not be disclosed by the escrow agent except upon written order of the court. The purpose of maintaining confidentiality is to protect the defendants' concerns regarding disclosure of the amounts that they deposit into the escrow fund inasmuch as knowledge of such amounts would allow calculation of any sums defendants determine should be paid in satisfaction of any obligation they have to a plaintiff covered by this order. The escrow agent shall report to the Court from time to time the sums that are deposited in the account together with information supplied to the agent to determine if the amount deposited is the amount require to

be paid under the terms of this order. The escrow agent shall confer with the defendants and the court to determine the appropriate form that should be completed and accompany any payment to be made to the escrow agent to allow the escrow agent to verify the accuracy of any payment made. The escrow agent shall provide Plaintiffs' Liaison Counsel with a bimonthly report showing only the aggregate of the previous two months' deposits, disbursements, interest earned, financial institution charges, if any, and current balance.

f. If the fund exceeds the amount needed to make payments as provided in this order, the Court may order a refund to those plaintiffs who have contributed to the fund. Any such refund will be made in proportion to the amount of the contributions.

3. **Modifications**

The Court reserves the power to modify the terms of this order, but no changes imposing any additional burden or obligation on plaintiffs in actions in a state court that has imposed this obligation on such parties in an order that incorporates or references this order will be made without the approval of the presiding state court judge.

| IT IS SO ORDERED. | |
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| ENTERED: | |
| | Honorable John R. Tunheim |

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| 10 | IN RE ST. JUDE MEDICAL, INC., MDL Docket No. 1396 | | |
| 11 | SILZONE HEART VALVES PRODUCTS LIABILITY LITIGATION | | |
| 12 | EIABILIT LITICATION | | |
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| 15 | PRETRIAL ORDER NO. | | |
| 16 | ESTABLISHING PLAINTIFFS' LITIGATION EXPENSE FUND TO | | |
| 17 | COMPENSATE AND REIMBURSE ATTORNEYS FOR SERVICES PERFORMED AND EXPENSES INCURRED FOR COMMON BENEFIT | | |
| 18 | TERRORIED TRADERING TO THE STATE OF THE STAT | | |
| 19 | The Court finds that this order is entered to provide for the fair and equitable | | |
| 20 | sharing among plaintiffs of the cost of special services performed and expenses incurred by | | |
| 21 | attorneys acting for the common benefit of all plaintiffs in this complex litigation. | | |
| 22 | Plaintiff's Litigation Expense Fund to be Established | | |
| 23 | Transfer & Exergetion Paperse I and to be Established | | |
| 24 | The Court shall establish insured interest bearing escrow accounts to receive and | | |
| 25 | disburse funds as provided in this order. The Court will, by future order, designate an escro- | | |
| 26 | agent to manage the account. These funds will be held as funds subject to the direction of the | | |
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1. <u>Assessment</u>

- All Plaintiffs and their attorneys (except those exempted as provided a. herein) who, (i) either agree or have agreed – for a monetary consideration - to settle, compromise, dismiss, or reduce the amount of a claim; or (ii) with or without a trial, recover a judgment for monetary damages or other monetary relief, including compensatory and/or punitive damages, with respect to a St. Jude Medical, Inc. Silzone® related claim are subject to ar assessment of the "gross monetary recovery," as provided herein.
- b. Defendants are directed to withhold this assessment from amounts paid to plaintiffs and their counsel, and to pay the assessment directly into the fund as a credit against the settlement or judgment. If for any reason the assessment is not or has not been so withheld, the plaintiff and his counse are jointly responsible for paying the assessment into the fund promptly.
- No orders, praecipes or notices of dismissal or discontinuance, of any c. plaintiff's claim, subject to this order, shall be filed unless accompanied by

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removed to, this court and treated as part of the coordinated proceeding known as *In re: St. Jude Medical, Inc., Silzone® Heart Valves Products Liability Litigation* including cases later remanded to a state court. The assessment in such cases shall be six (6) percent of the "gross monetary recovery," except for those cases described in subsections (iii) and (iv) below.

- ii. Applies to the other federal Silzone® cases which are not transferred to this court under MDL 1396 or which are transferred back to a transferor court by this Court or by the MDL panel for further proceedings. The assessment in such cases shall be six (6) percent of the "gross monetary recovery, except for those cases described in subsections (iii) and (iv) below.
- iii. Applies to cases in a state court to the extent so ordered by the presiding judge of that court, or in the event a state court plaintiff, through counsel, consents, by written agreement with the Plaintiff's Leadership Committee or Plaintiffs' Liaison Counsel, to be subject to an MDL fee assessment. The assessment in such state court cases is limited to six (6) percent of the "gross monetary recovery."
- iv. Shall not apply to cases removed from state court to federal court and then remanded to state court (based upon an order of improper removal) that have not at any time been transferred to MDL-1396 (unless subsection (iii) above applies).

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> The court reserves the right to relieve, wholly or partly, a plaintiff from the obligation of this order upon a showing of exceptional circumstances.

Disbursements

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- Upon order of the Court, payments may be made from the fund to attorneys who provide services or incur expenses for the joint and common benefit of plaintiffs in addition to their own client or clients. Attorneys eligible are limited to Plaintiffs' Liaison Counsel and members of the Plaintiffs' Leadership Committee, and other attorneys called upon by them to assist in performing their responsibilities, State Liaison Counsel, and other attorneys performing similar responsibilities in state court actions in which the presiding state court judge has imposed similar obligations upon plaintiffs to contribute to this fund. All time and expenses are subject to proper and timely submission (each quarter) of contemporaneous records certified to have been timely received by Steven E. Angstreich, Esq. of Levy, Angstreich, Finney, Baldante, Rubenstein & Coren, P.C. in accord with this Court prior orders.
- Payments will be allowed only to companies for special services b. performed, and to reimburse for special expenses incurred, for the joint and common benefit of all plaintiffs.
 - Payment may, for example, and without limitation, be made for services and expenses related to the obtaining, reviewing, indexing and paying for

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hard copies or computerized images of documents from the defendants; to conducting "national" and "state" depositions; and to activities connected with the coordination of federal and state litigation. The fund will not, however, be used to pay for services and expenses primarily related to a particular case, such as the deposition of a treating physician, if such activity results in some incidental and consequential benefit to other plaintiffs.

- Payments will not exceed the fair value of the services performed or the d. reasonable amount of the expenses incurred, and, depending upon the amount of the fund, may be limited to a part of the value of such services and expenses.
- All payments required to be made shall be made by defendants to the e. escrow agent. Payment to the escrow agent shall fully discharge the defendants' obligation under this order. The payments to be made to the account shall not be disclosed by the escrow agent except upon written order of the court. The purpose of maintaining confidentiality is to protect the defendants' legitimate concerns regarding disclosure of the amounts that they deposit into the escrow fund inasmuch as knowledge of such amounts would allow calculation of any sums defendants determine should be paid in satisfaction of any obligation they have to a plaintiff covered by this order. The escrow agent shall report to the Court from time to time the sums that are deposited in the account together with information supplied to the agent to determine if the amount deposited is the amount require to

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